

REMARKS

The undersigned wishes to thank the examiner for the courtesies extended by her during a telephone interview held on July 3, 2002. Because the subject matter of the interview is reflected throughout this amendment, no separate summary has been provided. A written summary will be provided at the examiner's request.

Claims 11, 12 and 14-32 were pending in the present application. Claim 28 is canceled without prejudice. Claim 11 is amended. Support for the amendment to claim 11 can be found in lines 21-33 on page 4 of the original specification. Therefore, the claim amendment does not raise any issue of new matter. Accordingly, entry of the present Amendment and reconsideration of various rejections are respectfully requested. The amendment does not change the scope of the invention, but instead merely serves to help accentuate one of the differences between the claimed invention and the art.

Applicant has concurrently filed a Supplemental Information Disclosure Statement, including two references cited in European Patent No. 0 845 999, which is the European counterpart of the present application. Applicant respectfully requests that the examiner consider these references and make them of record.

Claims 11, 12 and 14-32 stand rejected for allegedly containing new matter.

Claims 11, 12 and 14-28, as well as claims 29-32 have been rejected pursuant to 35 U.S.C. § 112, first paragraph, for allegedly failing to contain an adequate written description of the invention at the time of filing. Applicant respectfully traverses, as that rejection would be applied to the claims as amended hereby. In essence, the Patent Office has taken the position that although each of the claim limitations in dispute are found literally in the specification, the specification does not adequately describe them in every possible combination, a position that, with all due respect, has no legal foundation. Clearly applicant was in possession of a formulation that provided at least 60% viability following compression at the time of filing. Indeed, that is specifically exemplified. Applicant was also in possession of a tablet having a friability of between 0.1 and 1.0, as that was expressly described in the specification. Moreover, the entirety of the invention involved maximizing the amount of viable live bacteria following compression by providing a compression vehicle that maximized same. Clearly there was a written description of the invention at the time of filing.

The examiner notes that there is but a single example and argues that that example is not sufficient to support the newly limited genus claims. In this, the examiner is, with all due

(100-40)
only 60%
but
not above
not all
lactic
bacteria

respect, absolutely wrong. There is no requirement that applicants provide exemplification of every disclosed combination within a range explicitly described and claimed to support written description. Indeed, that is not even a requirement of enablement, something not at issue here. Because patent applications are constructive reductions to practice, applicant need have no examples and, as long as they actually describe the ranges and recitations claimed, there must be written description support.

This is particularly true in this case where applicant is using the same words as found in the specification to further define the invention. As stated in *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1115 (Fed. Cir. 1991), the issue is "[d]oes the specification convey clearly to those skilled in the art, to whom it is addressed, *in any way*, the information that appellant invented that specific compound claimed?" (Emphasis added). It is clear that applicant was in possession of a method of providing (at least) 60% viable bacteria following compression. It is also clear that applicant was in possession of tablets having a friability of between 0.1 and 1.0 at the time of filing. The rejection, therefore, must be withdrawn. There is no doubt that applicant was in possession of the invention now claimed when the application was filed.

Claims 11, 12 and 14-32 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. The office action asserts that "it is uncertain what is 'force sufficient' which is required to maintain bacterial viability at the level of at least 60% as claimed."

Applicant respectfully disagrees with this ground of rejection. Applicant notes that M.P.E.P. § 2173.05(b) requires that "the fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 221 USPQ 568 (Fed. Cir. 1984)."

In this case, the use of the phrase "force sufficient" in the amended claim 11 does not render the claim indefinite. In light of the specification, one of ordinary skill in the art would know the metes and bounds of the phrase "force sufficient" in the amended claim 11 as "force" that produces a tablet having a friability of between 0.1 and 1.0 and maintains bacterial viability of at least about 60%. Indeed, since the claim provides objective endpoints with which to measure success, one could readily determine what force is sufficient without undue explanation. Indeed, applicant has provided reliable criteria that can be used irrespective of the formulation.

The force required, on the other hand, will depend upon the formulation, rendering precise description difficult and even possibly misleading. The term is as clear and definite as the subject matter will allow. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claims 11, 12 and 14-28 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent 5,531,989 ("the '989 patent") in view of U.S. Patent 4,806,368 ("the '368 patent"), U.S. Patent 5,536,526 ("the '526 patent"), U.S. Patent 5,422,346 ("the '346 patent"), U.S. Patent 4,396,631 ("the '631 patent") and U.S. Patent 4,021,545 ("the '545 patent").

Applicant respectfully points out that the office action fails to establish a *prime facie* case of obviousness under the standard of M.P.E.P. §2142 which states that:

to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

The office action does not meet at least the first and third requirements. Applicant respectfully points out that there is no teaching or suggestion in the prior art that these cited references can be combined. The "suggestion or motivation" criteria must be satisfied from the disclosure of the prior art reference or from the knowledge of persons skilled in the art (see M.P.E.P. § 2143.01), not by the use of hindsight in view of the present application (emphasis added).

In this case, without looking at the disclosure of the present application, a person of ordinary skill in the art would not know, from the disclosures of the '989 patent, the '368 patent, the '526 patent, the '346 patent, the '631 patent and the '545 patent, how to obtain the claimed method of making live bacteria-containing tablets having the advantages described in the specification, e.g. high viability of the bacteria in the tablet following compression. There is nothing in the art cited to lead one to pick and choose disparate elements from the numerous references and arrange them as applicant has done. Therefore, the office action does not satisfy the first criteria for establishing a *prime facie* case of obviousness under M.P.E.P. § 2143.01.

Moreover, the '989 patent, the '368 patent, the '526 patent, the '346 patent, the '631 patent and the '545 patent, even if combinable, do not provide teaching, suggestion or motivation to one of ordinary skill in the art on how to obtain the claimed method of preparing live bacteria-containing tablet and, in particular, one which is capable of maintaining at least about 60% bacterial viability at a tablet friability of between 0.1 and 1.0 following the compression. Therefore, the office action fails to satisfy the third criteria for establishing a *prime facie* case of obviousness under the M.P.E.P. § 2143.01 because the combination does not disclose "all the claim limitations" of the amended claim 11.

The present invention teaches a unique and counterintuitive solution to a unique problem, *i.e.*, to achieve high bacteria viability by compressing the bacteria into a tablet having a friability of between 0.1 and 1.0. Nothing in the combination of references proposed specifically recognizes the advantages of the claimed method or even contemplates all of its claimed limitations. As the specification clearly teaches, the problem facing applicant is the destruction of live bacteria in tablets during compression. Some of the references identified by the examiner do describe inulin as useful in "sustaining" bacteria. However, this sustenance has nothing to do with physically preventing the bacteria from being crushed. Instead, the inulin, in the cases cited by the examiner, can be thought of as a nutrient or something that supports the bacteria within a tablet over time or during use. Stated another way, the prior art is concerned with a problem that occurs after the claimed invention, namely, how to keep whatever bacteria survived compression alive and functional, either in storage or during use. This must be contrasted with the present invention, whose goal is to maximize the amount of bacteria that survives tablet formation. The present application is as indifferent to the fate of the bacteria following compression as the prior art is to the fate of the bacteria during compression. Since the art teaches neither the problem nor its solution, the claimed invention is not obvious.

Therefore, claims 11, 12 and 14-27 and 29-32, as amended, are nonobvious over the combination of the '989 patent, the '368 patent, the '526 patent, the '346 patent, the '631 patent and the '545 patent. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

In view of the claim amendments, the remarks and discussions amongst Examiner Afremova, Examiner Marks, Michael Teschner and the undersigned, applicant believes that all pending claims, *i.e.*, claims 11, 12, 14-27 and 29-32, as amended, are in condition for allowance.

Therefore, entry of this Amendment and the issuance of a Notice of Allowance with respect to claims 11, 12, 14-27 and 29-32 are earnestly solicited.

No fee, other than the one-month extension of time fee is required in connection with the filing of this Amendment. However, if any additional fees are required, the examiner is authorized to charge such fees to our Deposit Account No. 12-1095.

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Respectfully submitted,

By *Lance Y. Liu*
Lance Y. Liu
Registration No.: 45,379
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant

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